

BTG0010-100 (142480US02)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: **Lo and Wainscoat**

Serial No.: **09/872,063**

Group Art Unit: **1634**

Filing Date: **June 1, 2001**

Examiner: **J. Goldberg**

For: **Non-Invasive Prenatal Diagnosis**

I certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

On June 25, 2004

  
Paul K. Legaard Reg. No. 38,534

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made.

**This Supplemental Information Disclosure Statement is being filed:**

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ **before** the mailing date of a first Office Action on the merits.

- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
- ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or**
- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), a Petition requesting consideration of the Information Disclosure Statement and the Petition Fee of \$130.00 set forth in 37 C.F.R. § 1.17(i)(1) (see "Statement," "Petition," and "Fees" below).
- ☒ Copies of references AP-CH listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 is enclosed.

**EXCEPT THAT:**

- ☐ In view of the voluminous nature of reference @@, and the likelihood that this reference is available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for

priority under 35 U.S.C. § 120 have been made in the instant application.

- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

**Statement under 37 C.F.R. § 1.97(e)**

- ☐ The undersigned attorney hereby states that each item information contained in the Supplemental Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Supplemental Information Disclosure Statement.

**Fees**


- ☒ No Fee is owed by the applicant(s).
- ☐ The Supplemental Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$\_\_\_\_\_. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$180.00. This form is submitted in duplicate.

- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
- ☒ No fee or Statement is required under 37 C.F.R. § 1.97(b).

Respectfully submitted,

  
\_\_\_\_\_  
Paul K. Legaard, Ph.D.  
Registration No. 38,534

Dated: 25 JUN 2004  
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 5

**Complete if Known**

Application Number	09/872,063
Filing Date	June 1, 2001
First Named Inventor	Yuk-Ming Dennis Lo
Art Unit	1634
Examiner Name	Jeannine Anne Goldberg
Attorney Docket Number	BTG0010-100 (142480US02)

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AQ	Kamm et al., "Nucleic acid Concentration in Normal Human Plasma", <u>Clinical Chemistry</u> , 1972, Vol. 18(6):519-522.	
	AR	Leon et al., "Free DNA in the Serum of Rheumatoid Arthritis Patients", <u>Journal of Rheumatology</u> , 1977, Vol. 4(2): 139-143.	
	AS	Cox et al., "DNA Concentrations in Serum and Plasma", <u>Clinical Chemistry</u> , 1977, Vol. 23: 297.	
	AT	Raptis et al., "Quantitation and Characterization of Plasma DNA in Normals and Patients with Systemic Lupus Erythematosus" <u>Journal of Clinical Investigation</u> , 1980, Vol. 66: 1391-1399.	
	AU	Martin et al., "A Method for Using Serum or Plasma as a source of DNA for HLA Typing," <u>Human Immunology</u> , 1992, Vol. 33: 108-113.	
	AV	Emanuel et al., "Amplification of Specific Gene Products from Human Serum," <u>GATA</u> , 1993, 10(6): 144-146.	
	AW	Yamamoto, et al., "Anti-ssDNA and dsDNA antibodies in Preeclampsia"; <u>Asia Oceania J Obstet Gynaecol</u> . 1994 Mar; 20(1): 93-9. [PubMed Abstract cited only]	
	AX	Nawroz, et al., "Microsatellite alterations in serum DNA of head and neck cancer patients," <u>Nature Medicine</u> , 1996, Vol. 2: 1335-1337.	
	AY	Mulcahy, et al. "Cancer and mutant DNA in blood plasma," <u>Lancet</u> , 1996, Vol. 348: 628.	
	AZ	Chen et al., "Microsatellite alternations in plasma DNA of small cell lung cancer patients," <u>Nature Medicine</u> , 1996, Vol. 2: 1033-1035.	
	BA	Douglas et al., "Trophoblast in the Circulating Blood during Pregnancy" <u>American Journal of Obstetrics and Gynecology</u> , 1959, Vol. 78: 961-973.	
	BB	Walknowska et al., "Practical and Theoretical implications of fetal/maternal lymphocyte transfer," <u>The Lancet</u> , 7 June 1969, 1119-1122.	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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	BC	Strickland et al., "Invasion of the Trophoblasts", <u>Cell</u> , 1992, Vol. 71:355-357	
	BD	Simpson et al., "Isolating Fetal Cells in Maternal Circulation for Prenatal Diagnosis", <u>Prenatal Diagnosis</u> , 1994, Vol. 14:1229-1242	
	BE	Priority application GB 97044440.0; 4 March 1997	
	BF	Saiki, R.K. et al., "Primer-Directed Enzymatic Amplification of DNA With A Thermostable DNA Polymerase," <u>Science</u> , 1988, Vol. 2239:487-491	
	BG	Kwok et al., "Avoiding False Positives With PCR," <u>Nature</u> , 1989; Vol. 339:237-238.	
	BH	Camaschella, C. et al., "Prenatal Diagnosis Of Fetal Hemoglobin Lepore-Boston Disease On Maternal Peripheral Blood," <u>Blood</u> , 1990; Vol. 75:2102-2106.	
	BI	Cherif-Zahar et al., Molecular Cloning And Protein Structure Of A Human Blood Group Rh Polypeptide," <u>Proc. Natl. Acad. Sci., USA</u> , 1990; Vol 87:6243-6247.	
	BJ	Longo M.C., et al., "Use Of Uracil DNA Glycosylase To Control Carry-Over Contamination In Polymerase Chain Reactions," <u>Gene</u> , 1990; Vol. 93:125-128.	
	BK	Collin Y., et al., "Genetic Basis Of The RhD-Positive And RhD-Negative Blood Group Polymorphism As Determined By Southern Analysis," <u>Blood</u> 1991; Vol. 78:2747-2752.	
	BL	Frickhofen et al., "A Rapid Method Of Sample Preparation For Detection Of DNA Viruses In Human Serum By Polymerase Chain Reaction," <u>J. Virological Methods</u> , 1991; Vol. 35:65-72.	
	BM	Holland et al., "Detection Of Specific Polymerase Chain Reaction Product By Utilizing The 5'→3' Exonuclease Activity Of The Thermus Aquaticus DNA Polymerase," <u>Proc. Natl. Aca. Sci., USA</u> 1991, Vol. 88:7276-7280.	
	BN	Rebello M.T. et al., "Extraction Of DNA From Amniotic Fluid Cells For The Early Prenatal Diagnosis Of Genetic Disease," <u>Prenatal Diagnosis</u> , 1991; Vol. 11:41-46.	

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Art Unit	1634
Examiner Name	Jeannine Anne Goldberg
Attorney Docket Number	BTG0010-100 (142480US02)

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	BO	Bianchi D.W., et al., "Detection Of Fetal Cells With 47, XY, +21 Karyotype In Maternal Peripheral Blood," <u>Hum. Genet.</u> , 1992; Vol. 90:368-370.	
	BP	Elias S. et al., "First Trimester Prenatal Diagnosis Of Trisomy 21 In Fetal Cells From Maternal Blood," <u>Lancet</u> , 1992; Vol. 340:1033.	
	BQ	Le Van Kim et al., "Molecular Cloning And Primary Structure Of The Human Blood Group RhD Polypeptide," <u>Proc. Natl. Acad. Sci., USA</u> 1992; Vol. 89:10925-10929.	
	BR	Bennett et al., "Prenatal Determination Of Fetal RhD Type By DNA Amplification," <u>New England J. Medicine</u> , 1993; Vol. 329:607-610.	
	BS	Hamada H. et al., "Fetal Nucleated Cells In Maternal Peripheral Blood: Frequency And Relationship To Gestational Age," <u>Hum. Genet.</u> , 1993; Vol. 91:427-432.	
	BT	Lee L. G., et al., "Allelic Discrimination By Nick-Translation PCT With Fluorogenic Probes," <u>Nucleic Acids Research</u> , 1993; Vol. 21:3761-3766.	
	BU	Simpson et al., "Isolating Fetal Cells From Maternal Blood: Advances In Prenatal Diagnosis Through Molecular Technology," <u>JAMA</u> 1993; Vol. 270:2357-2361.	
	BV	Bianchi et al., "Fetal Cells In Maternal Blood: Determination Of Purity And Yield By Quantitative Polymerase Chain Reaction," <u>Am. J. Obstet. Gynecol.</u> , 1994, Vol. 171:922-926.	
	BW	Livak et al., "Oligonucleotides With Fluorescent Dyes At Opposite Ends Provide A Quenched Probe System Useful For Detecting PCT Product And Nucleic Acid Hybridization," <u>PCR Methods &amp; Applications</u> , 1995; Vol. 4:357-362.	
	BX	Bianchi et al., "Fetal Cell Quantitation In Maternal Blood Samples From Normal And Aneuploid Pregnancies," <u>Pediatr. Res.</u> 1996; Vol. 39:142A.	
	BY	Cheung M.C. et al., "Prenatal Diagnosis Of Sickle Cell Anaemia And Thalassaemia By Analysis Of Fetal Cells In Maternal Blood," <u>Nature Genetics</u> , 1996; Vol. 14:264-268.	
	BZ	Geifman-Holtzman O., et al., "Fetal RhD Genotyping In Fetal Cells Flow Sorted From Maternal Blood," <u>Am. J. Obstet. Gynecol.</u> , 1996; Vol. 174:818-822.	

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	CA	Heid et al., "Real Time Quantitative PCR," <u>Genome Research</u> , 1996; Vol. 6:986-994.	
	CB	Sekizawa A. et al., "Prenatal Diagnosis Of The Fetal RhD Blood Type Using A Single Fetal Nucleated Erythrocyte From Maternal Blood," <u>Obstet. &amp; Gynecol.</u> , 1996; Vol. 87:501-505.	
	CC	Aubin J.T., et al., Specificity And Sensitivity Of RhD Genotyping Methods By PCR-Based DNA Amplification," <u>British J. Haematology</u> , 1997; Vol. 98:356-364.	
	CD	Sohda S., et al., The Proportion Of Fetal Nucleated Red Blood Cells In Maternal Blood: Estimation By FACS Analysis," <u>Prenatal Diagnosis</u> ; August 1997; Vol. 17:743-752.	
	CE	Lo Y.M. Dennis et al., Prenatal Genetic Analysis From Maternal Blood," <u>Lab Medica International</u> , 1991, Vol. 8:25-27.	
	CF	Lo Y.M. Dennis et al., Culture Of Fetal Erythroid Cells From Maternal Peripheral Blood," <u>Lancet</u> , 1994, Vol. 344:264-265.	
	CG	Lo Y.M. Dennis et al., Prenatal Determination Of Fetal Rhesus D Status By DNA Amplification Of Peripheral Blood Of Rhesus-Negative Mothers," <u>Annals Of The N.Y. Academy Of Sciences</u> , 1994, Vol. 731:229-236.	
	CH	Fowke et al., "Genetic Analysis Of Human DNA Recovered From Minute Amounts Of Serum Or Plasma," <u>Journal Of Immunological Methods</u> , 1995, Vol. 180:45-51.	

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